DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 17, 2014

NeuroMetrix, Inc.
Mr. Rainer Maas
Director of QA/RA
62 Fourth Ave.
Waltham, MA 02451

Re: K140586
Trade/Device Name: ASCEND Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: August 18, 2014
Received: August 19, 2014

Dear Mr. Maas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140586

Device Name
ASCEND Electrode

Indications for Use *(Describe)*
The ASCEND Electrode is intended for use as disposable, conductive, adhesive interface between the user's skin and a transcutaneous electrical nerve stimulator.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
for
ASCEND Electrode

SPONSOR

NeuroMetrix, Inc.
62 Fourth Avenue
Waltham, MA 02451 USA

Contact Person: Rainer Maas
Telephone: (781) 314-2781
Date Prepared: March 6, 2014

DEVICE NAME

Proprietary Name: ASCEND Electrode
Common/Usual Name: Transcutaneous Electrical Nerve Stimulator Electrode
Classification Name: 882.1320 GXY
Cutaneous Electrode

PREDICATE DEVICE

NeuroMetrix SENSUS Electrode (K121816)

INTENDED USE

The ASCEND Electrode is intended for use as disposable, conductive, adhesive interface between the user's skin and a transcutaneous electrical nerve stimulator.

DEVICE DESCRIPTION

The ASCEND Electrode provides an electrically conductive interface between a transcutaneous electrical nerve stimulator and a user's skin. It is intended to be disposable and for single person use. It is provided non-sterile.

COMPARISON TO PREDICATE

The ASCEND Electrode has identical indications for use and technological characteristics as the cleared SENSUS Electrode (K121816). The only difference is that the ASCEND Electrode is labeled for over-the-counter use while SENSUS Electrode is labeled for prescription use. Many cutaneous electrodes intended for use with transcutaneous electrical nerve stimulators have been cleared by the FDA for over-the-counter use, e.g., the Axelgaard ValuTrode Neurostimulation Electrodes (K130987). Because the ASCEND Electrode has the same intended use and fundamental technology as these other electrodes, it is substantially equivalent to them.

GUIDANCE DOCUMENT

The recommendations of the FDA's "Draft Guidance for Industry and Staff: Class II Special Controls Guidance Document: Cutaneous Electrode (April 5, 2010)" were taken into account in preparing this 510(k) submission. The draft guidance addresses requirements for cutaneous electrodes which are defined as "*an electrode that is applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation*." This definition includes electrodes intended for use with transcutaneous electrical nerve stimulators. NeuroMetrix believes that the ASCEND Electrode complies with the special controls as outlined in the draft guidance, thereby providing additional assurance of safe and effective use of the ASCEND Electrode.

NON-CLINICAL TESTING

The ASCEND Electrode has the same technological characteristics as the predicate SENSUS Electrode that was validated with electrical and mechanical tests to show that the electrode met its target specifications over a range of operating and storage conditions. Verification and performance testing demonstrated that the electrode met user needs as reflected in the functional specification.

The ASCEND Electrode conforms to the following voluntary standards:

- ISO 10993-1: Biological evaluation of medical devices – Part 1: Evaluation and testing.

CLINICAL TESTING

NeuroMetrix determined clinical testing was not required.

CONCLUSION

The ASCEND Electrode is substantially equivalent to the predicate SENSUS Electrode.